genzyme
SURGICAL PRODUCTS

K001440 1 of 2

DEKNATEL PRODUCT GROUP
SEPRA PRODUCT GROUP
SNOWDEN PENCER PRODUCT GROUP
600 Airport Road
Fall River, MA 02720-4740
508-677-6600

NOV 13 2000

EXHIBIT A

510(k) Summary of Substantial Equivalence

NextStitch Cardiovascular Valve Suture

In accordance with the requirements of 21 CFR § 807, this summary is formatted with the Agency's final rule ".... 510(k) Summaries and 510(k) Statements..." and can be used to provide equivalence summary to anyone requesting it from the Agency.

Manufacturer

Genzyme Surgical Products Corp.
600 Airport Road
Fall River, MA 02720-4740

Contact Person

Mary E. Gray
Phone: (508) 677-6512
Fax: (508) 677-6663
e-mail: mary.gray@genzyme.com

Date Prepared

May 4, 2000

Device Information

Trade Name:	NextStitch™ Cardiovascular Valve Suture
Common Name:	Polyester surgical suture
Classification Name:	Nonabsorbable poly (ethylene terephthalate) surgical suture (per 21 CFR § 878.5000)

Predicate Device

Genzyme Surgical Products Polydek® and Tevdek® Polyester Nonabsorbable Surgical Suture

Intended Use

The NextStitch Cardiovascular Valve Suture is intended for use in soft tissue approximation and/or ligation in cardiovascular valve replacement procedures.

Device Description

The NextStitch consists of multiple double-armed needles, which are connected in sequence. The double-armed needle incorporates two sutures into a single needle. This configuration allows surgeon to simultaneously drive two sutures through the same needle hole.

EXHIBIT A

510(k) Summary of Substantial Equivalence Cont.

NextStitch Cardiovascular Valve Suture

Device Description Cont.

The NextStitch, ranging from U.S.P. sizes 4-0, 3-0, 2-0, and 0, is available undyed, dyed green (D & C Green No. 6) and a co-braid of the undyed and dyed Tevdek or Polydek suture materials with or without pledgets. The suture materials will alternate as undyed, dyed and a co-braid of undyed and dyed. The three suture "colors" provide for differentiation and will aid as a visual indicator to the surgeon when tying the sutures.

The suture materials, Polydek and Tevdek, are nonabsorbable, multifilament suture composed of high molecular weight, long-chain, linear poly(ethylene terephalate) and is coated with polytetraflouroethylene. The Polydek is coated with a light concentration while Tevdek is coated with a heavier concentration.

Substantial Equivalence

Current Polydek and Tevdek suture materials (N84-366/S2 and #K930378) consist of individual suture lengths with needle attachments at each end. The NextStitch consisting of either Polydek or Tevdek nonabsorbable surgical suture is configured with multiple double-armed sutures that are connected in sequence. Although the device configurations are different, the NextStitch is identical in materials and performance characteristics to Polydek and Tevdek Polyester Nonabsorbable Surgical Suture.

The cleared indications for use of the Polydek and Tevdek suture materials are for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological procedures. The NextStitch device indications for use will be more specific to cardiovascular valve replacement. This indication falls within the more general indications for use of the Polydek and Tevdek suture materials; therefore allowing a statement of substantial equivalence to the existing materials.

The determination of substantial equivalence for this device was based on a detailed device description, performance testing and conformance with voluntary performance standards, e.g. ISO 10993-1 Biological Evaluation of Medical Deices, U.S.P. Section 1475 - Nonabsorbable Surgical Sutures, and the FDA Guidance Document *"Alternate Suture Labeling Resulting from January 11, 1993 Meeting with HIMA.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2000

Ms. Mary E. Gray, RAC
Regulatory Affairs Specialist
Genzyme Surgical Products Corporation
600 Airport Road
Fall River, Massachusetts 02720

Re: K001440
Trade Name: Nextstitch™ Cardiovascular Valve Suture
Regulatory Class: II
Product Code: GAT
Dated: August 16, 2000
Received: August 17, 2000

Dear Ms. Gray:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K001440

Device Name NextStitch™ Cardiovascular Valve Suture

Indications for Use

The NextStitch Cardiovascular Valve Suture is indicated for use in soft tissue approximation and/or ligation in cardiovascular valve replacement procedures.

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____

(Per 21 CFR § 801.109)

(Optional Format 1-2-96)

for Mark N Milhem

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K001440